REMARKS

Formal Matters

Claims 12-14, 16, 18-23, 25, 27-30 and 37-45 are pending after entry of the amendments set forth herein.

Claims 30 and 45 are amended for clarity. No new matter is added.

The Applicant respectfully requests reconsideration of the application in view of the remarks made herein.

Request for telephone interview

The Applicant respectfully requests a telephonic interview with Exr. Whiteman *prior to* the mailing of the next Office Action, if any rejections remain after consideration of the arguments set forth below. Applicant's representative James Keddie can be reached at (650) 833 7723.

Election/Restriction

The Applicant notes that claims 14, 16, 22, 23 and 42 are withdrawn because they are directed to neuroendocrine transcription factors other than ngn3, the species of neuroendocrine transcription factor elected for initial examination.

These withdrawn claims are dependent on generic claims 12, 19 and 41. Pursuant to the instructions set forth in MPEP §809.02(c), claims 14, 16, 22, 23 and 42 should be rejoined with claims 12, 19 and 41 upon allowance of claim 12, 19 and 41.

Accordingly, the Applicant respectfully requests rejoinder of claim 14, 16, 22, 23 and 42 if claims 12, 19 and 41 become allowable.

Allowable subject matter

The Applicant gratefully acknowledges the Examiner's indication that claims 27-29 recite allowable subject matter.

Rejection of claims under 35 U.S.C. § 112, second paragraph

Claim 30 is rejected as indefinite for reciting the term "the precursor cell".

Claim 30 has been amended to recite the phrase "the cultured gastrointestinal organ cell". Antecedent support for this phrase in found in claim 12.

In view of the foregoing, the Applicant respectfully requests withdrawal of this rejection.

Claim 45 is rejected as indefinite for reciting the term "The method of claim 1...".

Claim 45 has been amended to recite the phrase "The method of claim 12...".

In view of the foregoing, the Applicant respectfully requests withdrawal of this rejection.

Rejection of claims under 35 U.S.C. § 102

Claims 12, 13, 18, 19, 20, 21, 25, 30, 37-40, 41, 43 and 44 are rejected under 35 U.S.C. 102(f). The Office alleges that the Applicant did not invent the claimed subject matter. The sole basis for the Office's position is the assertion that the claims of US 6,703,220 encompasses some of the subject matter of the instant claims.

The Applicant respectfully submits that the basis of the Office's rejection is flawed. As such, the Applicant categorically disagrees with this rejection.

However, without any intention to acquiesce to the correctness of this rejection and solely to expedite prosecution, the Applicant submits herewith a declaration by Dr. Michael German under 37 C.F.R. § 1.132. Dr. German is a co-inventor of the claims of US 6,703,220 with Dr. Lin. In addition, Dr. German is the sole inventor of the claimed methods of the instant application.

In the declaration, Dr. German clarifies the contribution of Dr. Lin. Dr. Lin was a co-inventor of the US 6,703,220 claims with Dr. German since Dr. Lin made contributions with Dr. German to the claimed Ngn3 nucleic acid compositions and methods. Dr. Lin is not named as an inventor of the invention claimed in the present application since, as Dr. German indicates in his declaration, Dr.German alone conceived the claimed methods relating to production of insulin from a cell. Dr. Lin did not contribute to the conception of the methods claimed in the present application.

In view of the foregoing discussion, this rejection may be withdrawn.

Rejection of claims for Obviousness-Type Double Patenting

Claims 12, 13, 18, 19, 20, 21, 25, 30, 37-40, 41, 43 and 44 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-5 of U.S. Patent 6,703,220.

The Applicant categorically disagrees with this rejection.

However, solely to expedite prosecution, the Applicants provide herewith a terminal disclaimer over US 6,703,220.

The Applicant notes that the filing of a terminal disclaimer to obviate a rejection based on non-statutory double patenting is not an admission of the propriety of the rejection.[1] As such, while the Applicant firmly believes that this rejection fails to meet the requirements for Obviousness-Type Double Patenting set forth in MPEP § 804, a terminal disclaimer is filed to obviate the rejection.

Withdrawal of this rejection is respectfully requested.

Possible rejection of claims under 35 U.S.C. § 103(a)

The Office Action that several references are made in the Office Action to a rejection under 35 U.S.C. § 103(a)[2] over US patent 6,703,220, although no rejection has been made.

The Applicants respectfully submit that: a) the instant application claims priority to the application that gave rise to US 6,703,220; and b) the invention claimed in US 6,703,220 and the invention claimed in the instant application were commonly owned at the time the instant invention was made.

Accordingly, as setout in 35 U.S.C. §103(c), US 6,703,220 does not qualify as prior art to the instant application, and cannot render the instant claims obvious.

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[1] *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991). The court indicated that the "filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection."

[2] See, in particular, the second paragraph of page 6 and the first paragraph of page 7.

SUMMARY

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UCSF-129CIP.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: November 23, 2004 By: _____
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Attachments: Dr. German declaration
Terminal Disclaimer

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